



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,029	11/17/2000	Feng-Jing Chen	6200-0013	7055

23980 7590 04/03/2002

REED & ASSOCIATES
800 MENLO AVENUE
SUITE 210
MENLO PARK, CA 94025

EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 04/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,029

Applicant(s)

CHEN ET AL.

Examiner

Brian-Yong S Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,37,38,40-46 and 50-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3-12, 37-38, 40-46 and 50-94 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-12, 37-38, 40-46, 50 and 52-90, drawn to a fenofibrate containing composition.
- II. Claims 51 and 91-94, drawn to a method of treating lipid disorder with said composition.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product (described in US 4559345; US 4434167; 4246275; US 3956484; US 5087623; US 6090830; US 6110909; US 6172071 B1; US 613636; etc..., for example, 2-hydroxy-2-3-methylglutaryl coenzyme A reductase, Imidazole derivatives, WHI-P164, benzoxazepine compounds, HMG-CoA reductase & a niacin combination, chromium picolinate, N-(phenoxyalkanoyl)peptide derivatives, etc...).

If applicant elects Group I invention, it is subject to further restriction as followings:

- I(a) Claims 1, 3-4, 37-38, 40-41, 44-46, 52-53, drawn to a composition comprising fenofibrate and vitamin E substance combination.

I(b). Claims 5-12, 42-43, 54-65, 75-79, drawn to a composition comprising combination of fenofibrate and a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

I(c). Claims 66-74 and 80-90, drawn to a composition comprising fenofibrate and a vitamin E substance in combination with a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

Inventions I(a)-I(c) are directed to different fenofibrate-solubility-enhancing combinations, namely i) A(fenofibrate) + B(vitamin E substance), ii) A(fenofibrate) + C (trialkyl citrate, lactone, a nitrogen-containing solvents, and/or combinations thereof) and iii) A(fenofibrate)+B(vitamin E substance)+C (trialkyl citrate, lactone, a nitrogen-containing solvents, and/or combinations thereof).

The several inventions above are independent and distinct, each from the other, as they have acquired a separate status in the art and require independent searches. It is noted that a reference to one enhanced combination of drugs would not be a reference to another enhanced combination of drugs under 35 U.S.C. 103. Should applicant traverse on the ground that are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing (combination A+B) to be obvious variants of (combination A+C) and (combination A+B+C) respectively or clearly admit on the record that this is the case.

The several inventions above are independent and distinct, each from the other, as they have acquired a separate status in the art as a separate subject matter for inventive

effect and require independent searches. It is noted that a reference to one composition would not be a reference to another composition under 35 U.S.C. 103. Further, the claims read on a multitude of fenofibrate-solubility-enhancing solubilizing agents which would require many field of searches that would be an undue burden on the Examiner. Therefore, restriction for examination purposes if proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read "zohreh fay", written in black ink.